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| APPLICATION NO.   | FILING DATE | FIRST NAMED INVENTOR  | ATTORNEY DOCKET NO.     | CONFIRMATION NO. |
|---|-------------|-----------------------|-------------------------|------------------|
| 10/073,968  | 02/14/2002  | Cyril J. Schweich JR. | 7528.0002-15            | 8329             |
| 22852   | 7590        | 06/03/2008            | EXAMINER                |                  |
| FINNEGAN, HENDERSON, FARABOW, GARRETT & DUNNER<br>LLP<br>901 NEW YORK AVENUE, NW<br>WASHINGTON, DC 20001-4413 |             |                       | EVANISKO, GEORGE ROBERT |                  |
|   |             |                       | ART UNIT                | PAPER NUMBER     |
|   |             |                       | 3762                    |                  |
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|   |             |                       | 06/03/2008              | PAPER            |

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

|                              |                        |                     |
|------------------------------|------------------------|---------------------|
| <b>Office Action Summary</b> | <b>Application No.</b> | <b>Applicant(s)</b> |
|                              | 10/073,968             | SCHWEICH ET AL.     |
|                              | <b>Examiner</b>        | <b>Art Unit</b>     |
|                              | George R. Evanisko     | 3762                |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

1) Responsive to communication(s) filed on 25 March 2008.

2a) This action is **FINAL**.                            2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

4) Claim(s) 34-36,38-45,47-55,57,59,60 and 80-91 is/are pending in the application.

4a) Of the above claim(s) 50 and 51 is/are withdrawn from consideration.

5) Claim(s) \_\_\_\_\_ is/are allowed.

6) Claim(s) 34-36,38-45,47-49,52-55,57,59,60 and 80-91 is/are rejected.

7) Claim(s) \_\_\_\_\_ is/are objected to.

8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All    b) Some \* c) None of:

- Certified copies of the priority documents have been received.
- Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
- Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

1) Notice of References Cited (PTO-892)

2) Notice of Draftsperson's Patent Drawing Review (PTO-948)

3) Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_.

4) Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.

5) Notice of Informal Patent Application

6) Other: \_\_\_\_\_.

## **DETAILED ACTION**

### ***Continued Examination Under 37 CFR 1.114***

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 3/25/08 has been entered.

### ***Election/Restrictions***

Claims 50 and 51 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 12/18/06.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 34-36, 38-45, 47-49, 52-55, 57, 59, 60, and 80-91 rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The subject matter which was not described in the original specification is the member having a "recess corresponding in one of shape and size to the structure, and wherein the structure includes a cross-sectional dimension

that is different than a cross-sectional dimension of the connector" in combination with the other elements in the claim(s). The original specification does not show completely from all angles the member, recess, and connector or fully describe the combination of the three and it can not be determined if the "recess correspond[s] in one of shape and size to the structure" since the recess could be square or bigger or smaller than the structure and/or the metes and bounds of "correspond" have not been set forth. In addition, the original specification did not state that the structure includes a cross-sectional dimension that is different than a cross section dimension of the connector and therefore the dimensions could be the same.

Finally, for claims 85, 87, 89, and 91, the original specification did not describe or show an opening smaller than the structure. The opening could be larger than the structure and held by other means, such as adhesive.

#### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later

invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 34-36, 38-45, 47-49, 52-54, 57-60 and 80-91 are rejected under 35 U.S.C. 103(a) as being unpatentable over O'Connor (5450860).

O'Connor discloses a ligament, 12, (the claimed connector) that is approximately 10-20 cm, elongated, is capable of extending across at least one chamber due to its size, and can be cut to the proper size of the application (e.g. col. 5, lines 54-65), the use of sutures/pledgets (e.g. 40, 42, 48) at both ends (the claimed members) and other places along the ligament (e.g. col. 10, lines 48-55) and shows that the ligament can have an elongated or circular plegget/member having holes in figures 16, 17, 6, etc. For claims 36-39 and 60, the second connector is consider to be one of the pledgets since it joins the members through the ligament, is encased in heart tissue and is straight. Finally, O'Connor is capable of meeting the functional use recitations presented in the claim, such as having at least two portions of the outer wall displaced inwardly from the unrestricted portion, reconfigure the chamber, being located at the anterolateral surface, etc., since O'Connors ligament and sutures are used on heart valves, can be used for other applications (e.g. col. 7, line 20, col. 10), and is capable of being placed through the heart chamber and sutured to the epicardial surface using the sutures and/or pledgets to obtain the claimed intended use recitations. It is noted that the size of the heart the claimed device is meant for, the size of the device, and/or whether it is a animal or human heart has not been set forth in the claims and therefore the size of the device used in O'Connor is not particularly relevant as

long as it can meet the structural elements and is capable of meeting the functional use recitations presented in the claims.

O'Connor does not disclose a member including a recess for receiving a ball structure, the recess corresponding in one of shape and size to the structure and having an opening smaller than the structure and receiving the connector, and wherein the structure includes a cross-sectional dimension that is different than a cross-sectional dimension of a connector. It would have been an obvious matter of design choice to a person of ordinary skill in the art to modify the device of O'Connor with a member including a recess for receiving a ball structure, the recess corresponding in one of shape and size to the structure and having an opening smaller than the structure and receiving the connector, and wherein the structure includes a cross-sectional dimension that is different than a cross-sectional dimension of a connector, because Applicant has not disclosed that a member including a recess for receiving a ball structure, the recess corresponding in one of shape and size to the structure and having an opening smaller than the structure and receiving the connector, and wherein the structure includes a cross-sectional dimension that is different than a cross-sectional dimension of a connector provides an advantage, is used for a particular purpose, or solves a stated problem. One of ordinary skill in the art, furthermore, would have expected Applicant's invention to perform equally well with sutures and pledges as taught by O'Connor, because it provides the predictable results of a connection that does not (or minimally) damage the surrounding tissue and allows for non-traumatic use of the device and method to treat the patient. In addition, it is well known in the art to provide a member including a recess for receiving a ball structure, the recess corresponding in one of shape and size to the structure and having an opening smaller than the structure and

receiving the connector, and wherein the structure includes a cross-sectional dimension that is different than a cross-sectional dimension of a connector (e.g. a button type member) to provide the predictable results of a conventional connector and member that effectively distributes the pressure of a wide area.

Therefore, it would have been an obvious matter of design choice to modify O'Connor to obtain the invention as specified in the claim(s).

Claims 34-36, 38-45, 47-49, 58-60 and 80-91 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fleischman et al (6132438).

Fleischman discloses a suture, 126, (the claimed connector) that is tied to each member, (and therefore each is considered a separate first or second connector) and goes through the heart wall (figure 32 b) and shows the convex shaped members, 120, and how they can be substituted for the members, 116, in figures 31a and 31b. Also for claims 36-39 and 60, the second connector is considered to be the combination of an anchor and suture since it joins the members through the suture, is encased in heart tissue and is straight.

In addition, another interpretation of Fleischman is that Fleischman discloses in figures 31a, b, and c the plurality of members (far left and right anchors, 116) and connectors (suture 126, each connected to separate anchors, in combination with top and bottom anchors 116).

It is noted that the claim does not state that the second connector directly joins the members. Finally, Fleischman is capable of meeting the functional use recitations presented in the claim, such as having at least two portions of the outer wall displaced inwardly from the unrestricted portion, reconfigure the chamber, being located at the anterolateral surface, etc.,

since Fleischman's suture and anchors are used on the heart and the suture and anchors are capable of being placed through the heart chamber with the anchors being used on the epicardial surface and the suture tightened to obtain the claimed intended use recitations. It is also noted that the size of the heart the claimed device is meant for, the size of the device, and/or whether it is a animal or human heart has not been set forth in the claims and therefore the size of the device used in Fleischman is not particularly relevant as long as it can meet the structural elements and is capable of meeting the functional use recitations presented in the claims.

Fleischman does not disclose a member including a recess for receiving a ball structure, the recess corresponding in one of shape and size to the structure and having an opening smaller than the structure and receiving the connector, and wherein the structure includes a cross-sectional dimension that is different than a cross-sectional dimension of a connector. It would have been an obvious matter of design choice to a person of ordinary skill in the art to modify the device of Fleischman with a member including a recess for receiving a ball structure, the recess corresponding in one of shape and size to the structure and having an opening smaller than the structure and receiving the connector, and wherein the structure includes a cross-sectional dimension that is different than a cross-sectional dimension of a connector, because Applicant has not disclosed that a member including a recess for receiving a ball structure, the recess corresponding in one of shape and size to the structure and having an opening smaller than the structure and receiving the connector, and wherein the structure includes a cross-sectional dimension that is different than a cross-sectional dimension of a connector provides an advantage, is used for a particular purpose, or solves a stated problem. One of ordinary skill in the art, furthermore, would have expected Applicant's invention to perform equally well with the

anchors/members as taught by Fleischman, because it provides the predictable results of a connection that does not (or minimally) damage the surrounding tissue and allows for non-traumatic use of the device and method to treat the patient. In addition, it is well known in the art to provide a member including a recess for receiving a ball structure, the recess corresponding in one of shape and size to the structure and having an opening smaller than the structure and receiving the connector, and wherein the structure includes a cross-sectional dimension that is different than a cross-sectional dimension of a connector (e.g. a button type member) to provide the predictable results of a conventional connector and member that effectively distributes the pressure of a wide area.

Therefore, it would have been an obvious matter of design choice to modify Fleischman to obtain the invention as specified in the claim(s).

Claims 34-36, 38-45, 47-49, 52-55, 57, 59, and 60 are rejected under 35 U.S.C. 103(a) as being unpatentable Melvin (5957977).

Melvin discloses cords and elements, e.g. 86, 53, 58, 54, that function as elongated connectors between each member (e.g. 70 A and 70B, figures 2 and 6) with the members being circular, convex, and/or pad like (e.g. figure 5A, 6). As seen in figure 6, Melvin's elongated connector, such as the combination of elements 86, 52, and cord attached to bottom pad 80, extends across at least one chamber.

Melvin is capable of meeting the functional use recitations presented in the claim, such as having at least two portions of the outer wall displaced inwardly from the unrestricted portion, reconfigure the chamber, being located at the anterolateral surface, etc., since Melvin device is

used on the heart, is capable of being inflated and maintained at the pressure, applying uniform pressure or applying an indentation against one point (e.g. col. 3, lines 45-52). In addition, it is noted that the use of “static” occurs in the preamble.

Melvin does not disclose a member including a recess for receiving a ball structure, the recess corresponding in one of shape and size to the structure and having an opening smaller than the structure and receiving the connector, and wherein the structure includes a cross-sectional dimension that is different than a cross-sectional dimension of a connector. It would have been an obvious matter of design choice to a person of ordinary skill in the art to modify the device of Melvin with a member including a recess for receiving a ball structure, the recess corresponding in one of shape and size to the structure and having an opening smaller than the structure and receiving the connector, and wherein the structure includes a cross-sectional dimension that is different than a cross-sectional dimension of a connector, because Applicant has not disclosed that a member including a recess for receiving a ball structure, the recess corresponding in one of shape and size to the structure and having an opening smaller than the structure and receiving the connector, and wherein the structure includes a cross-sectional dimension that is different than a cross-sectional dimension of a connector provides an advantage, is used for a particular purpose, or solves a stated problem. One of ordinary skill in the art, furthermore, would have expected Applicant’s invention to perform equally well with yolk/cushion/members as taught by Melvin, because it provides the predictable results of a connection that does not (or minimally) damage the surrounding tissue and allows for non-traumatic use of the device and method to treat the patient. In addition, it is well known in the art to provide a member including a recess for receiving a ball structure, the recess corresponding in one of shape and size to the structure and

having an opening smaller than the structure and receiving the connector, and wherein the structure includes a cross-sectional dimension that is different than a cross-sectional dimension of a connector (e.g. a button type member) to provide the predictable results of a conventional connector and member that effectively distributes the pressure of a wide area.

Therefore, it would have been an obvious matter of design choice to modify Melvin to obtain the invention as specified in the claim(s).

Claim 55 is rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over O'Connor (or claim 57 of Fleishman). O'Connors sutures and pledgets are meant for the heart and to be implantable and therefore are biocompatible. In addition, O'Connor uses an example of CV-2 Goretex suture which is biocompatible. (Fleishman is also meant to be implanted and therefore the connector would be biocompatible)

In the alternative, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the implantable device of O'Connor (or Fleishman) with biocompatible materials since it was known in the art that implantable devices use biocompatible materials to provide the predictable results of not having the body reject the device and so that an infection does not occur.

#### ***Response to Arguments***

Applicant's arguments with respect to the claims have been considered but are moot in view of the new ground(s) of rejection necessitated by amendment

***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to George R. Evanisko whose telephone number is 571 272 4945. The examiner can normally be reached on M-F 6:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on 571 272 4955. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/George R Evanisko/  
Primary Examiner, Art Unit 3762

GRE  
5/29/08